FDA Hearing: Use of Social Media Tools for Promotion of FDA Regulated Medical Products

Issue #5: Internet Adverse Event Reporting

Karla Stricker Anderson

Managing Director

Pharmaceutical and Life Sciences Advisory

PricewaterhouseCoopers LLP

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Introduction

- PricewaterhouseCoopers work in interactive marketing and social media within the pharmaceutical industry

Background

- The web as a community

  - Conversation, comments and chatter about the use of drugs is common place on the web

  - Defining an adverse event among these unstructured conversations within web communities can be very difficult

  - Manufacturers can play varying roles in this conversation: Observant, participant, or host. Depending on their role, their ability to gather sufficient adverse event information can be challenging

  - There is a general acknowledgement that any identification of adverse events on the web needs to be reported through established processes if information is available

- Guidance for adverse event reporting needs to be across two distinct types of web/social media channels

  - Company owned, operated, or sponsored sites or content

  - All other sites

Company owned, operated, or sponsored sites or content

- Manufacturers have the ability to set rules of engagement and establish a structure for adverse event reporting

- Collaborate with sponsored sites on reporting, monitoring and information sharing

All other sites

- Challenges

  - Volume

  - Use of pseudo names and anonymous postings

  - Incomplete information

  - No mechanism to complete process

  - Country of origin

Sample comment

> Comment from: 25-34 Male on Treatment for less than 1 month (Patient)
>
> i m going though oral sergerory (pulling allteeth) and while im down the sergeon gave me this medicaton. this med has made possile to sleep. the only thing that i have noticed is that you need to be careful while on this makes you dizzy while standing and made me car sick but other than that it is a major "butt-kicker" medication!
>
> Published: October 18, 2008 ::

Source: RxList.com

Considerations

- Consider establishing guidelines for company owned, operated, or sponsored sites or content. Allow other sites to be self-regulated.

- Manufacturers should increase awareness and encourage inbound adverse event reporting

- There may be a need for a new model –from individual based adverse reporting to one that captures trends and patterns in patient communities that triggers further analysis